Real-life data of bevacizumab, carboplatin and gemcitabine in recurrent platinum-sensitive ovarian cancer

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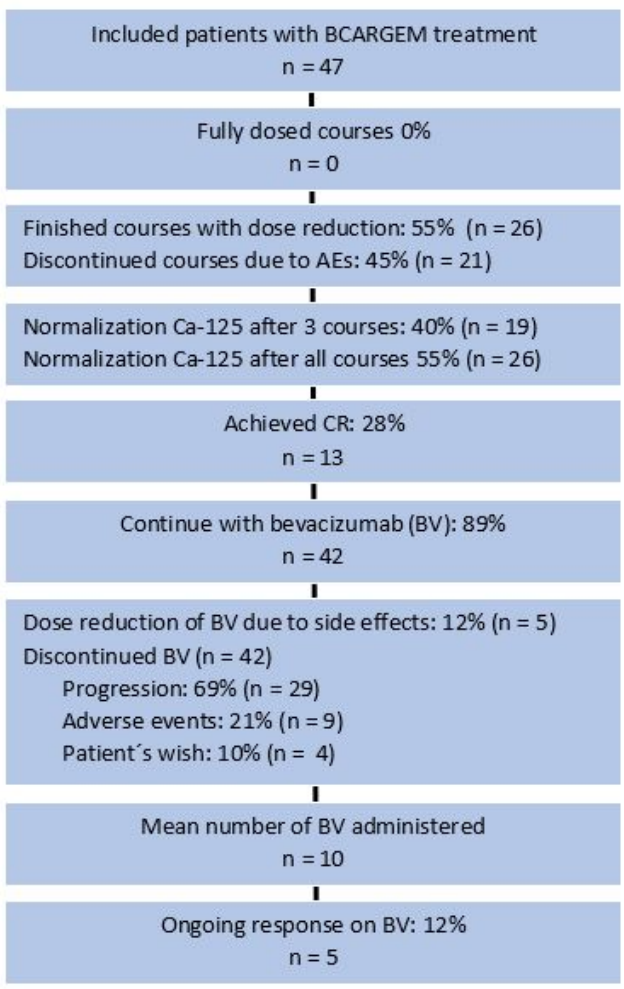
Background and objectives

- Ovarian cancer is still the most mortal gynaecological cancer in the western world, because 80% of the patients will relapse after achieving a good response after initial treatment.
- Almost 40% of the patients with ovarian cancer are 70 years of older.
- The OCEANS trial[1] –published in 2012- showed an improved progression free survival (PFS) for patients with platinum-sensitive recurrent ovarian cancer (ROC) treated with carboplatin, gemcitabine plus bevacizumab (BV) followed by maintenance therapy of BV till progression.
- There is no real life information yet available on the effectiveness and tolerance of this one randomized clinical trial (RCT) in clinical practise.
- Therefore, the aim of this study was to assess what the real time efficacy and tolerance of treatment with BCARGEM was in patients with platinum sensitive ROC.
- The secondary aim was to explore if the efficacy and toxicity differs between the patients < 70 years and patients ≥ 70 years.

Methods

All patients with platinum-sensitive ROC and treated with carboplatin, gemcitabine and BV in the UMC Utrecht Cancer Center were retrospectively included. All data were obtained from medical records. The primary outcome was PFS; secondary outcomes were relative dose intensity (RDI), adverse events (AEs) leading to dose modifications, and overall survival (OS).

Figure 1 . Flow chart of patient inclusion



Results

Table 1: Effectiveness and toxicity

Variable	Total	< 70 years n = 30	≥ 70 year n = 17	p-value
Progression (months)	41	27 (90%)	14 (82%)	0.450
Mean progression free survival (95 % CI) (months)	11.9 (8.6-15.3)	12.6 (8.6-16.6)	10.8 (4.8-16.7)	0.442 (log rank)
Death (months)	31 (66%)	18 (60%)	13 (76.5%)	0.252
Mean overall survival (95% CI) (months)	19 (14.1-24.0)	19.8 (14.3-25.2)	18.1 (8.9-27.3)	0.918 (log rank)
Mean RDI (min-max)	67.7% (14-92%)	71%	62%	0.080
RDI **< 85%** **85-99%** **100%**	 41 (89%) 5 (11%) 0	 25 (86) 4 (14) 0	 16 (94) 1 (6) 0	0.405
Mean courses carboplatin/gemcitabine	5.3 (1-6)	5.5	4.9	0.071
Non-haematological AEs				
Fatigue	9 (19%)	5 (17%)	4 (24%)	0.566
Hypertension	7 (15%)	5 (17%)	2 (12%)	0.650
Mucositis	5 (11%)	4 (13%)	1 (6%)	0.426
Carboplatin allergy	8 (17%)	4 (13%)	4 (24%)	0.371
Cerebrovascular event	1 (2%)	0 (0%)	1 (6%)	0.362
Thrombus	1 (2%)	0 (0%)	1 (6%)	0.362
Hematological AEs				
Anemia	4 (8%)	4 (13%)	1 (6%)	0.0426
Grade 2	2	1	1	
Grade 3	2	2	0	
Trombocytopenia	13 (28%)	7 (23%)	6 (36%)	0.199
Grade 1	7	3	4	
Grade 2	2	2	0	
Grade 3	2	1	1	
Grade 4	2	1	1	
Neutropenia	41 (87%)	27 (90%)	14 (82%)	0.450
Grade 2	4	2	2	
Grade 3	27	19	8	
Grade 4	10	6	4	

- The mean PFS of the 47 patients with platinum-sensitive ROC and treated with BCARGEM was 11,9 months. The mean OS was 19 months.
- The average RDI for BCARGEM was 67%. None of the patients reached a RDI of 100%.
- In most patients (87%) neutropenia grade ≥ 3 led to dose modifications or discontinuance of BCARGEM.
- The mean PFS, OS, and RDI were lower in the patients ≥ 70 years compared to the patients < 70 years although not significant.

Conclusion

- PFS of real-life patients treated with BCARGEM is lower compared to the OCEANS trial; 11,7 versus 12,4 months.
- The RDI of BCARGEM is very low reflecting the many AEs (predominantly grade 3) leading to dose modifications or discontinuation
- The efficacy and toxicity of BCARGEM seems lower ≥ 70 years
- This study underlines the fact that results of RCTs with strict in-and exclusion criteria do not represent actual outcomes in clinical care (the selected study patient does not match the patient we face in real time).

Figure 2 . Kaplan-Meier Estimates of PFS

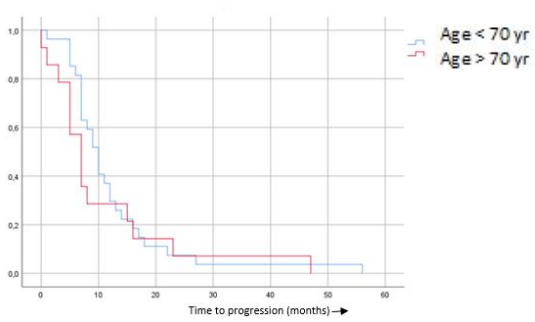
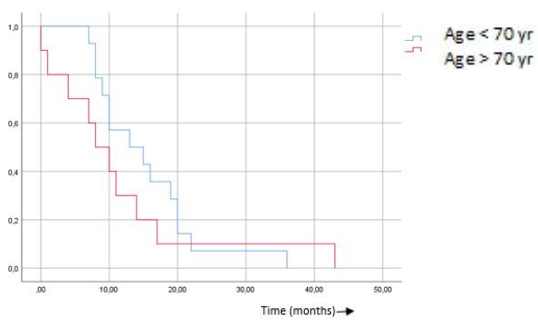


Figure 3 . Kaplan-Meier Estimates of OS



[1] Aghajanian; JCO 2012 (30): 2039-2045

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